

AMENDMENTS TO THE CLAIMS

This listing of claims replaces all previous versions, and listings, of claims pending in this application.

Listing of Claims

- 1-2. (canceled)
3. (original) A method of synthesis of an amonafide analog comprising combining a mitonafide analog comprising a 3-nitro group, ammonium formate, and a catalyst in an organic solvent to reduce said 3-nitro group.
4. (original) A method of synthesis of amonafide comprising combining mitonafide, ammonium formate, and a catalyst in an organic solvent.
5. (previously presented) A method of making naphthalimide salt comprising:
reacting a naphthalimide comprising at least two amine groups with an inorganic or organic acid to form a naphthalimide salt, wherein at least 1.5 mole equivalents of said two amine groups of said naphthalimide are protonated.
6. (original) The method of Claim 5 wherein said inorganic acid is selected from the group consisting of hydrochloric acid, hydrobromic acid, sulfuric acid, nitric acid and phosphoric acid.
7. (original) The method of Claim 5 wherein said organic acid is selected from the group consisting of acetic acid, propionic acid, glycolic acid, pyruvic acid, oxalic acid, maleic acid, malic acid, malonic acid, succinic acid, hydroxy succinic acid, fumaric acid, tartaric acid, citric acid, benzoic acid, cinnamic acid, mandelic acid, methanesulfonic acid, ethanesulfonic acid, p-toluenesulfonic acid and salicylic acid.
- 8-14. (canceled)
15. (previously presented) An aqueous solution consisting essentially of a dissolved naphthalimide salt comprising at least two amine groups, wherein at least 1.5 mole equivalents of said two amine groups of said naphthalimide are protonated, said solution being suitable for administration by injection, said solution comprising a naphthalimide at between 1 and 250 mg/mL.

16. (previously presented) An aqueous solution of naphthalimide—according to claim 15 suitable for parenteral, intramuscular, subcutaneous, intravenous, intraperitoneal or intratumoral administration.

17. (previously presented) An aqueous solution of a naphthalimide salt comprising at least two amine groups, wherein at least 1.5 mole equivalents of said two amine groups of said naphthalimide are protonated, said solution being suitable for administration by injection, said solution comprising naphthalimide at between 10 and 100 mg/mL.

18. (original) The solution according to claim 17, wherein said solution is substantially free of sugars.

19. (original) The solution according to claim 17, wherein said solution further comprises a pharmaceutically acceptable carrier.

20. (original) The solution according to claim 19, wherein said carrier is provided at a concentration between about 0.1 to 100 mg/mL.

21. (original) The solution according to claim 17, wherein said solution is provided in a unit dosage form.

22. (previously presented) A method for manufacturing a sterile pharmaceutical composition comprising a naphthalimide diammonium salt suitable for administration to a human, said method comprising:

(a) solubilizing a naphthalimide diammonium salt having at least two amine groups in an aqueous solution; and

(b) adding a base to said aqueous solution to form a naphthalimide salt, wherein 1.5 mole equivalents of said two amine groups are protonated;

(c) sterilizing said aqueous solution.

23. (previously presented) A method according to claim 3 or 4 further comprising forming an amonafide analog salt, solubilizing said amonafide analog salt in an aqueous solution and sterilizing said aqueous solution.

24. (previously presented) A method of making a naphthalimide salt comprising dissolving a naphthalimide salt having two protonated amine groups in an aqueous solution and adding a base to form a solution of naphthalimide salt, wherein at least 1.5 mole equivalents of said two amine groups of said naphthalimide are protonated.

25. (previously presented) A method according to claim 25 further comprising sterilizing said aqueous solution.

26. (previously presented) A method according to claim 15 or 17 wherein said naphthalimide comprises amonafide.

27. (previously presented) A method of making a naphthalimide salt comprising titrating an aqueous solution of a naphthalimide having at least two amine groups, with an acid or a base to produce a naphthalimide solution where at least 1.5 mole equivalents of said two amine groups of said naphthalimide are protonated.

28. (previously presented) A method according to claim 27 further comprising sterilizing said naphthalimide solution where at least 1.5 mole equivalents of said two amine groups of said naphthalimide are protonated.